REMARKS

The Office Action of March 18, 2004, has been considered by the Applicant. In response, independent claim 13 has been amended to include the limitations of dependent claim 15, which has been cancelled. Claim 13 now clearly indicates that the urination disorders being treated by the method of the present invention includes urinary incontinences selected from the group consisting of urge incontinence, reflex incontinence, and overflow incontinence. Support for this amendment can be found in the specification. See, for example, page 6, lines 4-7.

Additionally, new claim 35 has been added to clearly indicate that the urination disorders set forth in independent claim 25 is ameliorated, or improved, by the methods and compositions of the present invention. Support for this amendment exists throughout the specification. See, for example, page 6, lines 3-4.

Furthermore, new claim 35 has been added to indicate that the urination disorders that are improved by claim 35 include those selected from the group consisting of urge incontinence, reflex incontinence, and overflow incontinence. The above amendments are being made for clarification purposes only.

In view of the above amendments to the claims and the following comments, reconsideration of the application is respectfully requested.

Rejections Under 35 U.S.C. § 102(e)

On page 2 of the Office Action, the Examiner rejected claims13, 15-19, and 25-29 under 35 U.S.C. § 102(e) as being anticipated by Adamou et al. (US Pub 2002/0164707 A1). Specifically, the Examiner states:

> Claims 13, 15-19, and 25-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Adamou et al. (US Pub 2002/0164707 A1). Adamou et al. teach a adrenomedullin as a CRGP analog and agonist for CGRP receptors, which are employed for therapeutic purposes, such as the treatment of Parkinson's disease, acute heart failure, hypotension, urinary retention, and osteoporosis (see section [0028], [0089] and figure 9). Thus, the reference anticipates the claimed method.

Applicant submits that Adamou et al. broadly indicates that agonists for CGPP receptors can be used for therapeutic purposes to treat a wide range of disorders including urinary retention. However, this is merely a broad brush, shotgun disclosure, including a very large number of potential uses for agonists for CGPP.

Furthermore, independent claim 13 of the present application is limited to a method of treating urinary incontinence selected from the group consisting of urge incontinence, reflex incontinence, and overflow incontinence. Urinary retention is not an embodiment of the present development. Furthermore, independent claim 25 is directed to a method for promoting passive extension of bladder smooth muscle comprising administering a composition comprising adrenomedullin. This method is not taught or suggested by Adamou et al. and, thus, is clearly different from the subject matter described.

In view of the above, the present development is believed to be novel over Adamou et al. and withdrawal of the rejection is requested.

Rejections Under 35 U.S.C. § 103

On page 3 of the Office Action, the Examiner states:

> Claims 13 and 15-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adamou et al. (US Pub 2002/0164708 A1) in view of Kitamura et al. (US Patent 5,910,416).
>
> Adamou et al. teach a adrenomedullin as a CRGP analog and agonist for CGRP receptors, which are employed for therapeutic purposes, such as the treatment of Parkinson's disease, acute heart failure, hypotension, urinary retention, and osteoporosis (see section [0028], [0089] and figure 9). Adamou et al. do not teach the modification to adrenomedullin as recited in claims 20-24 and 30-34.

However, Applicant's are of the view that the Examiner has over simplified the alleged disclosures of Adamou et al. and that this reference does not disclose and/or remotely suggest the present invention.

In this regard, Applicant invites the Examiner to review Examples 1 and 2, wherein the claimed invention is based on the finding that adrenomedullin "has the effect of promoting extension of bladder smooth muscle" for the treatment of a urinary incontinence selected from the group consisting of urge incontinence, reflex incontinence, and overflow incontinence. Such diseases are caused by insufficient

extension of bladder smooth muscle.

Furthermore, as demonstrated, for example, by Figure 3, adrenomedullin does not inhibit contraction of the urinary bladder due to acetylcholine and, thus, the present invention provides a significant improvement over the prior art by providing a remedy for ameliorating urinary disorders without inhibiting urinary bladder contraction and without exhibiting side effects. This is shown on page 3 of the specification.

Moreover, while Adamou et al. describes that a CGRP analog including adrenomedullin can be used for the treatment of urinary retention. This is based in the diuretic effect of the CGRP/adrenomedullin. To further emphasize this point, Applicant draws the Examiner's attention to Israel et al. (submitted herewith), which shows that the diuretic effect is based on the effect of adrenomedullin on the central nervous system. It is not suggested that adrenomedullin directly affects the bladder. Therefore, such a diuretic effect enables the treatment of urinary retention; however, such an effect does not enable the treatment of urinary incontinence, and overflow incontinence, as shown in the present invention.

Accordingly, Adamou et al. fails to teach or suggest that adrenomedullin can be used for the treatment of urinary incontinence. In fact, quite to the contrary, Adamou et al. uses adrenomedullin for promoting urinary excretion, while the claimed invention uses adrenomedullin for treating a urine leakage, such as incontinence.

Additionally, the Examiner previously indicated that Kitamura et al. (U.S. Patent No. 5,639,855) discloses adrenomedullin as a peptide having a hypotensive effect. However, there is no disclosure or teaching therein to use adrenomedullin for ameliorating urination disorders.

In view of the above, it is submitted that Adamou et al. does not anticipate or make obvious the present invention, either alone or in combination with Kitamura et al. Therefore, the present invention must be recognized as novel and non-obvious over the prior art. Withdrawal of this rejection is requested.

CONCLUSION

For the reasons detailed above, it is respectfully submitted all claims remaining in the application (Claims 13 and 16-36) are now in condition for allowance. Early notification to that effect is earnestly requested.

In the event the Examiner considers personal contact advantageous to the disposition of this case, he is hereby authorized to call Richard M. Klein, at telephone number 216-861-5582, Cleveland, OH.

A check in the amount of $18.00 is enclosed for the appropriate fees required for this amendment. If, however, it is determined that additional fees are due, or there is an overpayment of fees, authorization is hereby given for deduction or crediting of those fees, from Deposit Account No. 06-0308.

Respectfully submitted,

FAY, SHARPE, FAGAN,
MINNICH & McKEE, LLP

June 7, 2004
Date

Richard M. Klein
Reg. No. 33,000
1100 Superior Avenue
7th Floor
Cleveland, Ohio 44114-2579
(216) 861-5582

Certificate of Mailing

Under 37 C.F.R. § 1.8, I certify that this Amendment is being

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Date	Signature / Printed Name
June 7, 2004	**Lynda S. Kalemba**

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